



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,437	11/14/2003	J. Francois Eid	EID-P-1	7044
44702	7590	12/17/2004	EXAMINER	
OSTRAGER CHONG FLAHERTY & BROITMAN PC 250 PARK AVENUE, SUITE 825 NEW YORK, NY 10177			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,437	Applicant(s) EID, J. FRANCOIS	
	Examiner Samuel G Gilbert	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/10/2004; 8/31/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 3/10/2004 and 8/31/2004 have been considered. Two references have been lined through because publication dates have not been provided.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tunnel located on the distal tip of the distal prosthetic must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of

the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 7, 10, 24, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 - in line 2, "in spaced and is parallel" is unclear. Should "is" also be --in-- or deleted?

Claim 4 - it is unclear what device dimension is being set forth.

Claim 7 - the claim sets forth the numbers and grooves are on the handle. The examiner believes the numbers and grooves are position on the shaft not the handle as shown in the drawings.

Claim 10 - it is unclear what device dimension is being set forth.

Claim 24 - it is unclear what method step decreases post operative scarring.

Claim 26 - "the shaft opening" lacks antecedent basis.

Claims 26 and 27 - it is unclear how the prosthesis is secured to the insertion tool to enable the prosthesis to be implanted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 8, 9, 11, 17-19 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishell(4,653,485).

Claims 1, 6, 9, 11 - Fishell teaches a device -30- including an elongate body -32- having a handle -38- and a hole -34- or -36- at apposing end -32a-(receptacle). The surfaces are smooth.

Claim 4 - the diameter of the elongated body is .25 inches which is within the claimed range.

Claim 8 - the end sphere -32a- is being considered to be convex, fusiform (tapered on the distal and proximal end of the sphere) and smooth edge and finish.

Claim 11 - is replete with functional language that does not result in a structural difference between the claim and the prior art device. The device of Fishell is capable of conforming and supporting as claimed.

Claim 17 - element -10- is a cylinder, the examiner is taking the inside portion of element -10- surrounding ball -32a- as a cradle, a fluid reservoir is not shown but set forth in column 3, line 33. Element -12- is a means for connecting. Fishell does not set forth a pump chamber or means for controlling. However it is the examiners position

Art Unit: 3736

that both are inherently required to be able to controllably fill the chambers -19- to provide an erection as is intended by the device of Fishell.

Claim 18 - silicone is set forth, column 4 line 6.

Claim 19 - the cradle is joined by an adhesive, column 3 lines 46-54.

Claim 21 - it is the examiner's position that the silicone used is a soft silicone.

Claim 22 - the method is set forth in column 4 lines 25-50.

Claim 23 the aperture is inherently smaller than required by an inflated cylinder because the device is inserted in a deflated state.

Claim 24 - since only a small incision is used post operative scarring is decreased.

Claim 25 - tool -30- is used to insert the implant.

Claims 6 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohamad(5,484,450). Mohamad teaches a device as shown in figure 5, including a shaft -120-, handle -110-, and a receptacle -122-. The receptacle includes a notch -124-.

Claims 13-16 - applicant's attention is invited to figure 1 and the description in column 1 lines 42-54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell (4,653,485).

Claim 10 - Fishell teaches a device as claimed as set forth above with regard to claim 6. However the dimensions for the entire device is not set forth. The shaft is .25 inches but the dimension for the end ball is not set forth. The ball is larger than the shaft but the exact dimension is not set forth. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any size as long as the selected dimension would be capable delivering the implant to the desired implantation site. In the absence of showing any criticality in the selected dimension the selection of any appropriate dimension would have been an obvious design expedient to one of ordinary skill in the art. In the instant case the selection of .39 inches diameter for the ball, 3/8 inches, would be slightly larger than .25 inches and would be within the expected range for the ball of Fishell.

Claim 20 - In the absence of showing any criticality in the selected dimension the selection of any appropriate dimension would have been an obvious design expedient to one of ordinary skill in the art. In the instant case the selection of 5mm distance from the distal end of the cradle would have been an obvious design expedient to one of ordinary skill in the art.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell (4,653,485) in view of Thompson (5,643,288).

Claims 2 and 3 - Fishell teaches a device as claimed but does not teach an angled shaft or a handle and shaft in spaced and parallel relation. Thompson teaches a surgical instrument for retrieving a suture having a straight handle and shaft or a shaft spaced and offset from the handle. Applicant's attention is invited to figure 11 and column 43-61. The changing of the shaft shape is desirable to make the surgical procedure easier, as taught by Thompson. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an offset parallel shaft in the device of Fishell to make the insertion of the penile prothesis easier as taught by Thompson. The procedure would be easier because an offset handle would be able to be turned to be out of the line of sight of the user and the handle could be grasped more easily because it would not be as close to the abdomen.

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell (4,653,485) in view of Furlow et al (4,244,370). Fishell teaches a device as claimed but does not teach measurement calibrated on the device. Furlow et al teaches an implantation device having measurement calibrations -16-. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include calibrations as taught by Furlow et al with the device of Fishell to gain the advantage of being able to determine the depth of the device as taught by Furlow et al.

Allowable Subject Matter

Claims 26 and 27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 6,319,272; 5,868,729; 5,749,877; 5,397,330; 5,382,256; 5,234,438; 5,109,869; 4,959,067; 4,964,417; and 3,929,138 teach related insertion type instruments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Gilbert', with a stylized flourish extending to the right.

Samuel G Gilbert
Primary Examiner
Art Unit 3736

sgg